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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
THANH, QUANG D	
ART UNIT	**PAPER NUMBER**
3764	15

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/917,655	Applicant(s) BOEKSTEGERS ET AL.	
	Examiner Quang D. Thanh	Art Unit 3764	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,10-22 and 24-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8,10-22 and 24-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 3-8, 10-22, 24-35 rejected under 35 U.S.C. 103(a) as being unpatentable over Tweden et al. (6,406,488) in view of Eno et al. (6,409,697 B2).

3. Re claims 1 and 29, Tweden discloses a device and a method of providing blood flow directly from a left ventricle of a heart chamber to a coronary artery (see abstract), comprising: providing a stent 10 (portions 13 and 14) (fig. 1) having sufficient strength to resist deformation from contractile cardiac forces (col. 2, lines 49-51) and flexibility in a compressed and a deployed state to permit passage to a myocardial site and remain patent when implanted (figs. 1-6, col. 3, lines 23-38); the stent includes a flared end 12 (fig. 1), and a covering 30 on an inner surface portion and outer surface portion of the stent (fig. 2, col. 4, lines 12-18); delivering the stent percutaneously in a compressed state into a passage at the myocardial site (col. 3, lines 34-36); and expanding the stent to deploy it in the passage (fig. 5-6, col. 3, lines 34-36) such that the flared end 12 seats around an end of the passage (fig. 1), except that Tweden's stent is an L-shaped and is not substantially straight. However, Eno teaches a transmyocardial implant 10 (fig. 1) comprising a straight elongate cylindrical tube or conduit 11 having a flared end 22/12 (fig. 1). Eno also suggests that while the tube 11 is preferably straight, the tube 11 could be bent so that the direction of blood from end 12 is not perpendicular to the arterial blood flow direction A (col. 5, lines 4-7). Therefore, it would have been obvious

to one of ordinary skill in the art at the time of invention was made to substitute the L-shaped stent of Tweden with the straight stent of Eno, as suggested and taught by Eno, since both are well known in the art as equivalent means for medical implant stent. Moreover, it would have been an obvious matter of design choice to modify the Tweden's device, to have a substantially straight stent, since applicant has not disclosed that having the substantially straight stent solves any stated problem or is for any particular purpose and it appears that the device would perform equally well with either designs. Furthermore, absent a teaching as to criticality that the stent is substantially straight, this particular arrangement is deemed to have been known by those skilled in the art since the instant specification and evidence of record fail to attribute any significance (novel or unexpected results) to a particular arrangement. In re Kuhle, 526 F.2d 553,555,188 USPQ 7, 9 (CCPA 1975).

4. Re claims 3-4, 10-12, 15-16, 24-26, and 30-31 Tweden discloses (claims 3 and 30) the covering 30 includes expanded PTFE material (col. 5, lines 2-3); (claims 4 and 31) wherein the covering covers substantially all of an inner and outer surface of the stent (col. 4, lines 50-54, fig. 2); (claims 10 and 24) the flared end 12 is placed in the passage to face the coronary vessel (fig.1); (claims 11-12 and 25-26) the coronary vessel is a coronary artery 82 and the heart chamber is a left ventricle 83 (fig. 1); (claims 15-16) delivering the stent includes delivering the stent percutaneously in a compressed state into a passage at the myocardial site (col. 3, lines 34-36).

5. Re claims 5-8,17-22, and 32-35, Tweden also discloses the stent including a hemocompatible and anti-thrombogenic agent such as heparin coating over the covering on the inner surface of the stent (col. 4, lines 28-31).

6. Re claims 13-14 and 27-28, with respect to the limitation "partial blockage", Tweden discloses the myocardial site is distal to a coronary blockage 81 (fig. 1), which appears to be a partial blockage. Alternatively, if blockage 81 is not viewed to be a partial blockage then it would be obvious for a coronary blockage to be either total or partial blockage and in either case the device and method taught by Tweden still apply.

Response to Arguments

7. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Tweden's device has all the claimed features except that it is L-shaped and is not substantially straight. However, Eno teaches that it is preferably for the device to have a straight implant rather than the L-shaped implant, which includes a portion to be placed within a

coronary vessel and a portion to be placed within the myocardium, because the size can be reduced and shape enhanced by elimination of the vessel portion (col. 1, lines 38-55). Since the suitability of the implant for minimally invasive or percutaneous procedure is influenced by the external size and shape of the implant (col. 1, lines 51-54), the straight implant would have an advantage of providing an enhance design for reducing a likelihood of damage to a coronary vessel from a high-velocity blood flow discharge (col. 1, lines 9-12). This teaching of Eno clearly would be a motivation for one of ordinary skill in the art to modify Tweden's device in order to implant a device for passing blood flow directly between a chamber of the heart and a coronary vessel with reduced likelihood of damage to a coronary vessel from a high-velocity blood flow discharge.

8. In response to applicant's arguments against the reference Tweden individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Regarding applicant's remarks that "Tweden explicitly teaches against the hypothetical modification proposed by the Examiner and to make such modification would render Tweden unsatisfactory for its intended purpose and destroy the explicitly taught principles of operation of Tweden", the Examiner respectfully disagrees. There is no unobviousness for modifying Tweden's to eliminate the vessel portion, as taught by Eno, so that it would gain the advantage of being an enhanced design suitable for minimally invasive or percutaneous procedure and reducing a likelihood of damage to a

coronary vessel from a high-velocity blood flow discharge (col. 1, lines 9-12). The modified straight- tube device would still be able to pass blood flow directly between a heart chamber and a coronary vessel (see Tweden's abstract), and thus still render Tweden satisfactory for its intended purpose. Therefore, since the proposed modification still render Tweden satisfactory for its intended purpose and does not result in a change in the principle of operation as explained above, the section 103 rejection of the pending claims based on the combination of Tweden and Eno is proper.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang D. Thanh whose telephone number is (703) 605-4354. The examiner can normally be reached on Monday-Thursday & alternate Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (703) 308-2698. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1148.

Quang D. Thanh
Patent Examiner
Art Unit 3764
January 15, 2004

Danton D. DeMille
Primary Examiner